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10/813,872	03/30/2004	Dominique Charmot	RLY 04031.102	5573

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EXAMINER	
YOUNG, MICAH PAUL	
ART UNIT	**PAPER NUMBER**
1618	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/813,872	CHARMOT ET AL.	
	Examiner	Art Unit	
	MICAH-PAUL YOUNG	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,10,16,17,20-24,31,32 and 45-68* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,10,16,17,20-24,31,32 and 45-68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment of Papers Received: Response dated 12/6/07

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 10, 16, 17, 20-24, 31, 46-48, 51-55, 57, and 61-68 rejected under 35 U.S.C. 102(b) as being anticipated by Gardon et al (USPN 3,874,907 hereafter '907). The claims are drawn to a pharmaceutical composition comprising an excipient and core-shell particles comprising a core component and a shell component where the core comprises a cation exchange resin and the shell comprises crosslinked synthetic polymers.

1. The '907 patent teaches as microparticle formulation comprising cationic exchange polymers (abstract). The microcapsules comprise a core and coating where the core comprises a cationic polymer such as sulphonic acid resin with a diameter between 100-2000 microns and a shell with a thickness between 1-50 microns (col. 12, lin. 44-60, example 1). As a ratio of shell thickness to core diameter this is 0.01:1-0.2:1 meeting the limitation of the claims. The shell polymers include crosslinked polymers of vinylic, methacrylic and ethylenic monomers (col. 6, lin. 63-68). The polymers of the shell are hydrophobic (col. 6, lin. 5-10). The saline solution that surrounds the core-shell particles would act as a pharmaceutical excipient.

2. Regarding the potassium binding (percentage of ions, selection of ion, etc.) limitations, it is the position of the Examiner that these limitations are inherently met by the '907 patent. The '907 patent provides microparticles with a core/shell morphology with the same polymers in the shell and core as those of the instant claims. The shells/skins and cores of the '907 patent are identical to those of the current claims. The cores comprise sulphonated acid resins while the shell/skin comprises polymerized vinyl, ethylenic or methacrylic monomers. These polymers arranged in the same way as the instant claims and exchange polymers of the surrounding environment (col. 14, lin. 12-26). For these reasons it is the position of the Examiner that the microparticles would inherently pass through the intestine without disintegrating, and bind at least 75% of the surrounding potassium, and remove the ions from the intestinal system inherently.

3. Regarding the removal of the potassium ions from the intestinal tract of the a human patient suffering from various kidney disorders, it is the position of the Examiner that such limitations are merely a future intended use and do not impart patentability on the products claimed. The products are identical to those of the prior art. Where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation. See also *Rowe v. Dror*, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997).

4. Regarding claims 31, 52, 53, 64 and 65, it is the position of the Examiner that these claims are merely product-by-process claims and their limitations are inherently met by the prior art. The shells of the '907 patent comprising vinyl, ethylene or methacrylic polymers, that are formed from the polymerization of vinyl, ethylene or methacrylic monomers. Even though

product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)

5. For these reasons at least the claims are anticipated by the '907 patent.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1, 10, 16, 17, 20-24, 31, 32 and 45-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Kamakura et al (USPN 6,280,717 hereafter '717) in view of Gardon et al (USPN 3,874,907 hereafter '907) and Heese et al (US

2002/0054913 hereafter '913). The claims are drawn to a microparticle comprising a core and a shell where the shell is a crosslinked polymer ethylenic, vinylic methacrylic and acrylic monomers, while the core polymer includes a cation exchange polymer comprising functional groups such as carboxylate, phosphate, sulfate, sulfonate, sulfamate and combinations thereof. The claims are also drawn to a method of treating various renal disorders wit the composition.

4. The '717 patent discloses a pharmaceutical composition useful in treating renal disease and failure comprising particles that comprise cation exchange polymers (abstract). The formulation comprises a cation exchange polymer such as a polystyrene calcium sulfonate (col. 2, lin. 48-50). The particles measure in size from 5-500 microns (col. 2, lin. 51-53). The formulation comprises excipients such as binders, gelling agents, flavors and sweeteners (col. 2, lin. 55-col. 3, lin. 30). The cation exchange polymers are combined with the excipients, extruded into granular cores and coated with polymeric coatings (examples). The reference is silent to the thickness of the polymer coating, however this would be well within the range of ordinary skill in the art to apply as seen in the '907 patent.

5. The '907 patent discloses a microparticle formulation comprising cationic exchange polymers (abstract). The microcapsules comprise a core and coating where the core comprises a cationic polymer such as sulphonic acid resin with a diameter between 100-2000 microns and a shell with a thickness between 1-50 microns (col. 12, lin. 44-60, example 1). As a ratio of shell thickness to core diameter this is 0.01:1-0.2:1 meeting the limitation of the claims. The shell polymers include crosslinked polymers of vinylic, methacrylic and ethylenic monomers (col. 6, lin. 63-68). The polymers of the shell are hydrophobic (col. 6, lin. 5-10). It would have been

obvious to include these particles into the pharmaceutical formulation of the '907 patent since they both comprise sulphonated core particles useful in cation exchange.

6. Regarding the potassium binding (percentage of ions, selection of ion, etc.) limitations, it is the position of the Examiner that these limitations are inherently met by the '907 patent. The '907 patent provides microparticles with a core/shell morphology with the same polymers in the shell and core as those of the instant claims. The shells/skins and cores of the '907 patent are identical to those of the current claims. The cores comprise sulphonated acid resins while the shell/skin comprises polymerized vinyl, ethylenic or methacrylic monomers. These polymers arranged in the same way as the instant claims and exchange polymers of the surrounding environment (col. 14, lin. 12-26). It is the position of the Examiner that the microparticles would inherently pass through the intestine without disintegrating, and bind at least 75% of the surrounding potassium, and remove the ions from the intestinal system inherently.

7. Regarding the removal of the potassium ions from the intestinal tract of a human patient suffering from various kidney disorders, it is the position of the Examiner that such limitations are merely a future intended use. The products are identical to those of the prior art. Where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation. See also *Rowe v. Dror*, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997).

8. Regarding product claims reciting the production of the polymer shells, it is the position of the Examiner that such limitations are merely product by process limitations and do not in and of them selves define patentable subject matter since the products of the '907 patent provide identical products with the same core/shell structure and materials as the instant claims as

discussed above. The Patent Office bears a lesser burden of proof in making out a case of prima facie obviousness for product-by-process claims because of their peculiar nature" than when a product is claimed in the conventional fashion. See *In re Fessmann*, 489 F.2d 742, 744, 180 USPQ 324, 326 (CCPA 1974). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. See *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir.1983)

9. The reference is silent to an additional enteric coating, however the addition of an enteric coating in order to increase the stability of the microparticle is well know in the art as seen in the '913 patent. The '913 patent discloses an enteric coated particles comprising cores and coating (abstract). The core has a cation exchange capacity [0038] and an enteric coating with a thickness from 20-60 microns [0044-0045]. The enteric coating would have been useful in protecting the cation exchange particles and for proper release in the intestine.

10. With these things in mind it would have been obvious to combine the particles of the core-shell particles of the '907 patent in to the pharmaceutical compositions of the '717 patent since the core-shell particles are useful in cation exchange utilities. Further the cores of each patent are the same. Both formulations comprise sulphonated cores coated by polymeric shells. The shell of the '907 patent would provide improved ion selection and improved treatment of renal disorders. The '717 patent would provide a pharmaceutical dosage form easier for digestion and administration in the form of syrups and confections. These pharmaceutical dosage forms would have an improved mouth feel and be easier to administer to patient with

difficulty swallowing. The '913 patent would provide the enteric coating tot he core-shell polymers improving the stability of the particles and provide proper administration of the particles in the appropriate portion of the intestine. It would have been obvious to combine these disclosures with an expected result of a stable formulation useful in treating renal disorders.

Double Patenting

1. Claims 1,10,16,17,20-24,31,32,45-65 of this application conflict with claims 3,4,14,15,18-22,29,30,34,36,40, and 51-75 of Applicant No. 10/813,872. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

2. Claims 1,10,16,17,20-24,31,32,45-65 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 3,4,14,15,18-22,29,30,34,36,40, and 51-75 of copending Application No. 10/814,749. Although the conflicting claims are not identical, they are not patentably distinct from each other because both set of claims recite pharmaceutical formulations comprising core-shell formulation comprising potassium-binding polymers that are crosslinked. The formulations both have shells with thicknesses up to 50 microns. These claims would act as obviating art over each other.
This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

11. Applicant's arguments filed 12/6/07 have been fully considered but they are not persuasive. Applicant respectfully argues that:

a. There would be not motivation for a person of ordinary skill to look to the particles of the Gardon patent since the particles remove urea, and other anions from an ex vivo environment, and not potassium from an in vivo environment.

b. Due to the ex vivo nature of the Gardon particles there is no motivation to combine the coatings of the Warchol patent.

12. Regarding argument a. and b., it remains the position of the Examiner that the Gardon patent taken in view of the Warchol disclosures would obviate the instant invention. The Examiner acknowledges that the particles of the Gardon patent are used in dialysis machines in an ex vivo capacity. However these particles are inherently identical to those of the instant claims, in that they remove ions from a surrounding environment. The context in which the particles remove the ions is completely arbitrary and unrelated to their function. It is the position of the Examiner that the particles would perform the same function in an environment, whether in the body or outside the body. The particles would be expected to perform the same in testing and preliminary evaluations as when taken internally. The Warchol patent merely adds pharmaceutical additives to the particles to make them more palatable and bioavailable. An enteric coating to protect the particles from premature disintegration and pharmaceutical excipients to prolong their stability through the GI tract. The particular ions absorbed are completely dependent on the environment. The particles have the same structure as those of the instant claims, the same core polymers with the same shell polymers present in the same

concentrations and ratios as the instant claims. The Warchol patent merely adds well known components to increase the bioavailability of the formulation.

13. Regarding the treatment of renal disorders, it remains the position of the Examiner that the combination would be able to treat such disorders since the particles of the Gardon are used in that capacity. The Gardon particles are used by dialysis patients to clear ions during the procedure. The method of the instant claims merely requires administration of the particles. The Warchol patent discloses the administration of particles in order to treat various conditions. Combining the core-shell particles of the Gardon with the excipients and enteric coating of the Warchol paten and administrating the particles internally as disclosed in the Warchol patent would have been obvious to one of ordinary skill in the art since administration is a basic treatment step to those of ordinary skill. Since the particles would have the same structure and components they would inherently absorb potassium, and screen out other competing ions. The shell and core would be present in the same ratio and would be able to treat various kidney disorders and be useful to dialysis patients. For these reasons the claims remain obviated.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on M-F 6:00-3:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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